REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on September 20, 2007, and the references cited therewith.

Claims 9 and 21 are amended, no claims are canceled or added; as a result, claims 9-18 and 20-21 are now pending in this application. Reconsideration and withdrawal of the rejections of the claims of the above-identified application in view of the amendments and remarks presented herein is respectfully requested.

Claims 9 and 21 has been amended to recite administering to an animal such as a pig at any stage of the animal's life post-weaning, through the animal's water source, a supplement comprising a water miscible and stable immunoglobulin concentrate the source of which is blood plasma from which the fibrin and albumin have been separated, said concentrate containing at least 15% by weight IgG. This amendment to recite that the supplement is derived from blood plasma and is administered post-weaning is supported, for example, at page 8, line 27 and page 12, lines 23-24 of the present specification.

I. The Rejection of Claims 9-18 and 21 under 35 U.S.C. §103(a)

Claims 9-18 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stott et al. (U.S. Patent No. 4,816,252) in view of Watanabe et al. (Japanese Patent No. JP 61-132143) and Elliot et al. (U.S. Patent No. 4,623,541). Claims 9 and 21 have been amended. However, to the extent the rejection applies to claims 9-18 and 21, Applicants respectfully traverse the rejection.

Applicants assert that the Examiner has not established a *prima facie* case of obviousness. The underlying factual determinations that must be made to resolve the obviousness question include (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness. Graham v. John Deere Co., 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

Although the cited references need not contain an explicit teaching, suggestion, or motivation to combine them to yield the claimed invention, the burden remains upon the

Examiner to provide sufficient reasoning to support a finding that the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. KSR Int'l v. Teleflex, 82 U.S.P.Q.2d 1385 (U.S. 2007). Applicants respectfully submit that the cited art and the reasoning supplied by the Examiner do not meet this standard.

The present claims are direct to a method of improving weight gain and growth, while decreasing morbidity and mortality in animals comprising administering to an animal at any stage of the animal's life, through the animal's water source, a supplement comprising a water miscible and stable immunoglobulin concentrate the source of which is blood plasma from which the fibrin and albumin have been separated. The concentrate contains at least 15% by weight IgG. The animal may be a pig, a cow, and a chicken. The water stable immunoglobulin concentrate is dispersed in the water in a concentration of from about 0.375 to about 3.0% by weight to afford a concentration of IgG in the water from about 0.1-0.75% by weight. The immunoglobulin concentrate may be administered in a dose of 0.5 g immunoglobulin/hd/day with one or more additives or nutrients selected from the group consisting of carbohydrates, vitamins, and minerals.

The Level of Ordinary Skill in the Art

It is respectfully submitted that the level of ordinary skill in the art is high: a practitioner would have at least an advanced degree in a life science such as biological chemistry or animal science.

The Scope and Content of the Prior Art and the Differences between the Claimed Invention and the Prior Art

Stott et al. (U.S. Patent No. 4,816,252)

Stott et al. disclose a product and process for transferring passive immunity to newborn domestic animals using ultrafiltered whey containing immunoglobulins (*see*, e.g., title). Stott et al. further disclose that their "filtered product is subsequently dissolved in a liquid such as colostrum, milk or water to achieve a desired Ig

concentration" (e.g., column 4, lines 64-66). Stott et al. also disclose that the "Ig solution is ingested by a newborn domestic animal such as a calf postpartum within the critical absorption period" (e.g., column 4, line 64 to column 5, line 1). Regarding the critical absorption period, Stott et al. disclose that:

> To use the filtered product to implement the last phase of the present invention and control the transfer of passive immunity to the newborn calf, a predetermined quantity of the filtered product is dissolved in a liquid such as colostrum, milk or water to produce a one or two liter Ig solution. This Ig solution is fed to the calf during the critical absorption period, generally within twelve hours and ideally within eight hours postpartum.

(e.g., column 13, lines 12-20). In short, Stott et al. disclose an immunoglobulin product derived from milk, not blood, that should be given to animals in liquid form within the "critical absorption period" (e.g., a maximum of twenty-four hours postpartum) to have any effect on achieving passive immunity.

Stott et al. also disclose that this "whey-derived product could also be used on a continuous basis as a food supplement for a calf, a mature cow or any other animal to enable the immunolically active immunoglobulin molecules in the product to attack pathogens present in the digestive system of the animal" (e.g., column 24, lines 56-61). To test this hypothesis, Stott et al. fed calves a filtered product having a seven percent Ig concentration in addition to normal high protein feed rations. Stott et al. disclose that the "product-fed calves appeared healthier and experienced a higher growth rate and lower morbidity than the control group calves. This test appeared to prove the utility of the whey-derived product as a feed supplement for either growing or mature animals" (e.g., column 25, lines 12-17). In short, Stott et al. disclose a whey-product having a low concentration of immunoglobulin that can be used as a feed supplement. However, unlike Applicants' claimed invention, the whey-product is not given in the water source to a calf post-weaning to provide higher growth rates and lower morbidity. Further, the whey-product contains only 7-12% Ig and is not derived from blood plasma.

Watanabe et al. (Japanese Patent No. JP 61-132143)

Watanabe et al. disclose a globulin-containing feed comprising a globulin-containing substance made from blood or milk of animal and an antimicrobial agent (*see*, e.g., abstract). Watanabe et al. further disclose that this feed is fed to immature pigs to produce improvement in weight and breeding efficiency.

Watanabe et al. disclose one method in which fibrin was removed with calcium chloride from blood plasma to obtain blood serum (*see*, e.g., page 263, right column, English Translation, Exhibit A). Fat-free powder milk and lactic acid bacteria were added to the blood serum. The composition was fermented, homogenized, spray dried, and fed to pigs. It is respectfully submitted that Watanabe et al. made no attempt to remove the albumin from this fermented composition.

Watanabe et al. disclose a second method in which milk serum was concentrated using filtration membrane with a molecular mass cut off of 13,000 to remove lactose and inorganic matter. The concentrated milk serum was mixed with a synthetic milk composition, and fed to young pigs. It is respectfully submitted that Watanabe et al. made no attempt to remove the serum albumin from this composition because "serum albumin . . . possesses a molecular weight on the order of sixty-six thousand Daltons" (e.g., column 8, lines 51-53, Stott et al. (U.S. Patent No. 4,816,252)) and would not be removed with by a filter with a molecular mass cut off of 13,000. In short, Watanabe et al. disclose compositions that contain serum albumin. However, unlike Watanabe et al., Applicants are not claiming use of a serum albumin-containing milk to produce improvement in weight and breeding efficiency in immature pigs. Instead, Applicants are using the water supply to deliver a water miscible and stable IgG concentrate to promote weight gain and growth to an animal at any stage of the animal's life, while decreasing morbidity and mortality.

Elliot et al. (U.S. Patent No. 4,623,541)

Elliot et al. disclose a purified immunoglobulin preparation from blood that is subsequently commingled with condensed skim milk and spray dried (*see*, e.g., abstract). Elliot et al. also disclose that the resulting product is employed in the formulation of milk

replacers for artificial rearing of neonatal pigs to provide a passive immunity to disease that is normally provided by sows' colostrum and later milk (*see*, e.g., abstract). Elliot et al. further disclose that the "survival amongst pigs supplemented with immunoglobulin prepared by the processed process (77.8%) was significantly greater and due to the presence of the immunoglobulin supplements" (e.g., column 6, lines 35-39). It is respectfully submitted that skim milk contains 0.52 % by weight of serum albumin (*see*, e.g., page 172, left column, 2nd paragraph, J. G. Brennen, "Food Dehydration, A Dictionary and Guide, Butterworth-Heinemann, Oxford, U.K., 1994, Exhibit B). In short, Elliot et al. disclose an albumin-containing milk replacer, which is derived from blood to be given to neonatal or infant pig, and which provides passive immunity. However, unlike Elliot et al. Applicants are using the water supply of the animals to deliver a water miscible and stable IgG supplement in water to promote weight gain and growth, while decreasing morbidity and mortality.

As such, it is respectfully submitted that none of the cited documents disclose or suggest administering to an animal such as a pig at any stage of the animal's life post-weaning, through the animal's water source, a supplement comprising a water miscible and stable immunoglobulin concentrate the source of which is blood plasma from which the fibrin and albumin have been separated, said concentrate containing at least 15% by weight IgG.

The Combination of Stott et al., Watanabe et al., and Elliot et al.

As stated by the Supreme Court in KSR v. Teleflex, "[t]he question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art." Id., at p. 14. Applicants assert that it would not obvious for a person of ordinary skill in the art to prepare and administer the Ig concentrate via the water supply to animals post-weaning, as recited in the pending claims.

There is no logical reason that one of ordinary skill in the art would combine the teachings of Stott et al., Watanabe et al., and Elliot et al. to arrive at a solution of the problem that Applicants have solved.

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)." M.P.E.P. §2143.07.

It is respectfully submitted that it is not logical by one of skill in the art to combine Stott et al. with Watanabe et al. For example, Stott et al. disclose that serum albumin is purposely removed from the immunoglobulin composition in order to increase the concentration of immunoglobulin (*see*, e.g., column 8, lines 48-59). If the serum albumin-containing milk of Watanabe et al. is added to the colostrum replacement of Stott et al., the concentration of immunoglobulin would be decreased and the colostrum replacement of Stott et al. would be rendered unsatisfactory for its intended purpose. As such, it is respectfully submitted that one of skill in the art would not logically combine Stott et al. with Watanabe et al.

Applicants assert it would not be logical for one of skill in the art to combine Stott et al., who disclose a colostrum replacement to be given within 24 hours of birth to transfer passive immunity, or a solid feed supplement, both of which have had the serum albumin removed, with Watanabe et al., who describe a globulin-containing milk-replacer containing serum albumin, and Elliot et al., who describe a milk replacer to be given to neonatal or infant pigs, to arrive at Applicants' method of improving weight gain and growth, while decreasing morbidity and mortality in animals by administering an immunoglobulin concentrate to animals via their water supply.

In order to arrive at the claimed method with the cited art, it would be necessary to select the liquid colostrum supplement designed for transferring passive immunity to an animal within 24 hours of birth of Stott et al., combine it with serum albumin-containing milk of Watanabe et al. or with the milk replacer of Elliot et al. while at the same time discarding (1) the solid feed composition of Stott et al., (2) the serum albumin of Watanabe et al., and (3) the albumin in the skim-milk of Elliot et al. Finally, it would be necessary to ignore the teachings of Stott et al. and Elliot et al. regarding the desirability of feeding the supplement to neonatal animals and administer it to animals post-weaning. "It is impermissible within the framework of section 103 to pick and

choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 147 U.S.P.Q. 391, 393 (CCPA 1965). It is respectfully submitted that the Examiner is engaging in impermissible picking and choosing among the three documents.

For at least the reasons described above, it is respectfully submitted that pending claims 9-18 and 21 are not obvious over Stott et al. in view of Watanabe et al. and Elliot et al. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

II. The Rejection of Claim 20 under 35 U.S.C. §103(a)

Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Stott et al. (U.S. Patent No. 4,816,252) in view of Watanabe et al. (Japanese Patent No. JP 61-132143) and Elliot et al. (U.S. Patent No. 4,623,541) as applied to claim 9 above, and further in view of Austin et al. (U.S. Patent No. 5,143,257). Applicants respectfully traverse the rejection.

Applicants to not disagree that appliances exist to administer medicaments or nutrients to animals in their water supply. For example, Austin et al. disclose a system for proportional liquid dispensing of two liquids, the first of which can comprise the main flow drinking water supplied to livestock or poultry and the second of which can comprise controlled quantities of medication or nutrient to be introduced into the drinking water (*see*, e.g., abstract). Although Austin et al. disclose that "it has been common industry practice to mix medication and or nutrients such as an antibiotic or vitamins dispensed in controlled dosages to the feed stuff or drinking water supply provided to the various animals" (e.g., column 1, lines 23-26), it is respectfully submitted that that Austin et al. do not suggest administering a concentrated water miscible immunoglobulin concentrate to the animals, as recited in the present claims.

As such, Applicants respectfully submit that pending claim 20 is not obvious over the combination of Stott et al. and Watanabe et al. and Elliot et al. applied to claim 9 above, and further in view of Austin et al. Applicants respectfully request

reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6971 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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